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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,665	01/13/2004	Oded Katzman	25794X	9619
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NATH & ASSOCIATES 1030 15th STREET, NW 6TH FLOOR WASHINGTON, DC 20005			NGUYEN, GEORGE BINH MINH	
			ART UNIT	PAPER NUMBER
			3723	

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/755,665

Applicant(s)

KATZMAN ET AL.

Examiner

George Nguyen

Art Unit

3723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2005.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
4a) Of the above claim(s) 24-36, 40-45 and 60-63 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-5, 7-11, 16-21, 37, 38 and 46-59 is/are rejected.
7) ☒ Claim(s) 6, 12-15, 22 and 39 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 13 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's election filed on May 09, 2005.

Claims 1-23, 37-39, and 46-59 are presented for examination. Claims 24-36, 40-45, and 60-63 were withdrawn from further consideration.

This application has been filed with formal drawings which are acceptable to the examiner.

Election/Restrictions

1. Applicant's election with traverse of Group I invention, claims 1-23, 37-39, and 46-59 in the reply filed on May 09, 2005 is acknowledged. The traversal is on the ground(s) that there is no serious burden on the examiner to examine all inventions from Group I to Group IV. This is not found persuasive because these inventions are distinct for the reasons given in the restriction and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The requirement is still deemed proper and is therefore made FINAL.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the limitations of "full-spatial mechanical and one optical true-position" in claims 19-21, and "a priory integral chuck" in claims 51-52, 55, and "being full register with one another" in claim 49.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-10, 11, 17, 19-21, and 23, 37, 38, 47, and 49-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. In claim 1, the claim is directed to a method of processing but there is no specific or positive steps being claimed in the body of claims. Thus, it is unclear what is the scope of the invention. It is recommended that Applicant recites specific steps rather than merely claiming the structural limitations of the apparatus. In line 4, the word "then" should have been "than". This error applies to claims 11, 17, 37, 38, 47.

6. In claim 49, it is unclear what is meant by "being in full register with one another".

7. In claims 51-53, 55, it is unclear what is meant by "a-priory integral chuck".

8. Claim 13 recites the limitation "the structural support material" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-5, 7-11, 16-18, 23, 49-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Galley'4,084,458.

With reference to Figures 1-9, col. 1, line 64 to col. 3, line 50, Galley discloses the claimed invention including the steps of :

- obtaining a lens blank 10.
- gripping the lens blank 10 by a gripping device 11.
- processing the lens blank 10 to obtain full spatial reference datum indications (col. 2, lines 17-23) and processing a first optical face of the lens (Figure 2). Please note that the diameter and the length of lens blank are broadly considered as full spatial reference datum indications.
- turning over the lens blank 10 and gripping it relying on said reference datum indications.

Regarding to claims 49-59, as well as understood in the meaning of "a priory integral chuck", in Figure 6, the part including reference surface 41 is considered as a priory integral chuck set forth in the claims. In Figure 7, the priory integral chuck is removed during processing of the second face 81 of the lens 80.

U.S. Patent April 18, 1978 Sheet 2 of 3 4,084,458

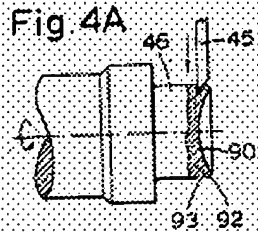
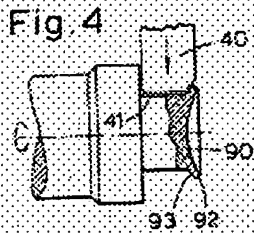


Fig. 5

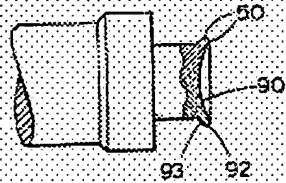
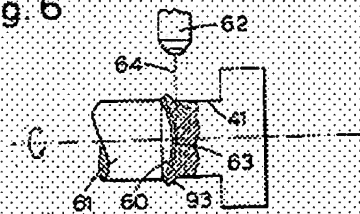


Fig. 6



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MANUFACTURE OF CONTACT LENSES

This application is a continuation-in-part of application Ser. No. 511,091, filed Oct. 1, 1974 and now abandoned.

This invention relates to the manufacture of contact lenses.

Contact lenses are currently produced by a machining process from lens blanks formed of the appropriate plastics material. In one current machining process, a lens lathe is employed to machine a first curved lens surface on the blank, the blank is removed and repositioned and the second lens surface is machined. The circumferential edge surface is formed by the intersection of the first and second curved surfaces, or by shearing through the peripheral portion of the partly formed lens. The resulting circumferential edge surface then generally has to be polished to the desired profile and dimensions. Alternatively, a yet further machining operation is performed on the partly formed lens in a lens edging machine, to machine the desired circumferential edge surface. This involves a further re-positioning step in a machine.

One object of the present invention is to provide a method of manufacturing a contact lens in which a circumferential edge lens surface of desired profile, dimension, and accuracy may more readily be achieved and reproduced.

According to the present invention in one aspect there is provided a method of manufacturing a contact lens from a lens blank, comprising machining the surface which will form the circumferential edge surface of the finished lens, before machining at least one of the two mutually opposed curved lens surfaces.

In another aspect there is provided a contact lens having its convex lens surface machined from a suitable blank subsequent to machining of its concave lens surface and subsequent to machining of its circumferential edge surface.

In a further aspect of the invention there is provided a machine for manufacturing a contact lens comprising a rotatable lens blank support, a first material removal tool arranged to traverse said support in an arc about an axis to form a first curved lens surface on a blank held by said support, and a second material removal tool arranged to traverse said support to form a circumferential edge surface on such blank, said support and said tools being arranged so that both said tool traversals may be effected without removing such blank from said support.

Embodiments of the invention will now be described by way of example, with reference to the accompanying drawings in which:

FIGS. 1, 2, 3, 4, 5, 6, 7, 8 and 9 show schematically inside elevation consecutive steps in the manufacture of a contact lens according to the invention, the curvature of the lens being rather exaggerated to assist explanation;

FIG. 4A shows a modification of the step of FIG. 4; and,

FIG. 10 is a schematic plan view of a machine according to the invention for machining contact lenses.

Referring to the drawings, FIG. 1 shows a lens blank 10 of the appropriate plastic material in a machinable condition. The blank 10 is mounted to a rotatable support 11, suitably by means of a thermo-plastic adhesive 12. The support 11 is adapted for reception in a chuck

or the like of a material removal machine such as a lens lathe. A particular preferred machine for carrying out the invention will be described below with reference to FIG. 10. The blank 10 is preferably in the form of a right circular cylinder with a pre-moulded dished end 13.

It will be understood that the contact lenses in their finished form, as shown in FIG. 9, present a concave lens surface 90 intended in use to sit peripherally against the eye ball, an opposite convex lens surface 91 of appropriate curvature to ameliorate the vision defect of the user and a circumferential edge surface 92 of tangible thickness. A frusto-conical surface 93 is also preferably provided and all the boundaries between the surfaces 90, 91, 92 and 93 are polished to a smooth condition.

Referring back to FIG. 1 a first step is preferably to reduce the blank 10, or at least a portion of the length thereof, to a desired diameter, e.g. 7 mm. This step also serves accurately to centre the rotating blank. The machining may be effected by axial traversal of a cutting tool 14, while the supported blank 10 is rotated about its longitudinal axis by the machine.

Referring to FIG. 2 the first concave lens surface 90 is machined by traversal of a radius cutting tool 20 in an arc about an axis 21.

Referring to FIG. 3 an edge forming tool 30 machines the desired circumferential edge surface 92 on the rotating supported blank 10. The tool 30 is conveniently fed forwards into material moving engagement with the blank immediately after the tool 20 has finished each traverse in its machining surface 90 as shown in FIG. 3. The tool 30 is conveniently mounted on a radius arm together with tool 20 to pivot about the same axis 21. The lens blank material may be somewhat brittle and for best results care is taken to traverse the tool 30 at controlled speed.

One defect of the currently used process is that it is difficult to machine an accurate edge surface after machining both the curved lens surfaces. In the method according to the present invention it will be appreciated that the circumferential edge surface 92 is machined while still bodily supported by the bulk 32 of the blank material behind the edge surface 92. That material 32 is then subsequently machined away to provide the convex surface 91 as will be described below. In addition, it will be appreciated that both the concave surface 90 and the edge surface 92 are machined without removing and repositioning the blank in the machine. That leads to enhanced accuracy in profile and dimensions of the edge surface 92, to enhanced accuracy in positioning of surface 92 relative to surfaces 90 and 91, and to enhanced ease in achievement and reproducibility of a desired surface 92.

It is possible in an alternative embodiment to machine the convex surface 91 and the edge surface 92 while the blank is in its first supported position and then subsequently to machine the concave surface 90; however the particularly described and illustrated method is preferred at the present time.

Referring to FIG. 4, a further tool 40 is then moved radially in to work on the rotating partly formed lens to machine a frusto-conical surface 93 and simultaneously to machine a right circular cylindrical surface 41. As with the edging step shown in FIG. 3 the best results are achieved by taking care to feed tool 40 at a controlled speed in view of the thinness of the tangible edge of the lens.

4,084,458

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As shown in FIG. 5, the circumferential boundaries 50 between the concave surface 90 and the edge surface 92, and between the edge surface 92 and the frusto-conical surface 93 are then polished to round them slightly.

Referring to FIG. 6, the polished partly-worked blank from FIG. 5 is moved from its support 11 and re-positioned the other way round with machined concave surface 90 stuck e.g. with thermoplastic adhesive 60 to a second support 61. A microscope 62 is then used to view the crown 63 of the concavity through the body of the material (which is of course transparent) perpendicular to the lens axis, as shown by vision line 64. The microscope is mounted to the machine and thus its position can be accurately determined by a dial gauge or the like when the crown 63 is centered in the cross-wires of the microscope. This use of a microscope 62 eliminates the necessity for physical measurements on the lens at this stage.

Referring to FIG. 7, a further tool 70 is then set in accordance with the indication of the position of the microscope 62, and traversed as shown by arrows 71 about axis 72 to machine the convex lens surface 91.

The machined lens 80 is then removed from the support 61 and boundaries 81 between the surface 91 and frusto-conical surface 93 are polished, to result in the finished machined lens 90 shown in FIG. 9.

The tools referred to are preferably diamond cutters but tungsten carbide or steel tools may sometimes be used instead.

FIG. 4A shows a modification in which a tool 45 is substituted for tool 40. As shown this forms only the frusto-conical surface 93. The microscope 62 can then be positioned to view the crown 63 through the original substantially cylindrical blank surface 46 if desired.

Referring to FIG. 10 there is shown very schematically a machine for making contact lenses according to the invention. The machine bed is basically that of a lens lathe and comprises a motor 100 for rotating a chuck 101 on a head stock 102. The chuck 101 is shown gripping the support 11 of FIGS. 1 to 5. Tools 20 and 30 are shown mounted on a table 103 on a radius arm 104 for movement as described about axis 21. The tools are adjustable as shown by arrows 105, 106 and 107, and gauges 108 indicate their longitudinal positions. Tool 40 and microscope 62 are movable as shown by arrows 109 and 110. An adjustable tool 111 serves to reduce the original blank 10 to a desired diameter as a first step as described. The surface 93 may be machined slightly rounded by appropriate shaped tools 40 and 45.

The method of manufacturing contact lenses (as well as the machine described herein), is applicable to all types of contact lenses, including both 'hard' contact lenses and 'soft' contact lenses. The manufacture of all types of contact lenses will benefit from the enhanced accuracy of the method of the present invention and the greater facility whereby such accuracy is achieved. Inasmuch as 'soft' contact lenses are machined according to the method of the present invention in their non-hydrated relatively hard state and subsequently swollen in an aqueous medium to their soft, operative condition, the ability to attain great precision is highly desirable since any imperfections in the non-hydrated state are magnified when the lens is swollen.

I claim:

1. In a method of manufacturing a contact lens having a first and second lens surfaces, said method including the steps of:

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a. centering a contact lens blank on the chuck of a lens lathe having at least a radius cutting tool and edge cutting tools means,

b. machining the centered blank with said radius cutting tool to form the first curved lens surface, and

c. machining the second opposite curved lens surface, the improvement comprising machining a peripheral edge portion with the edge tool cutting means while the blank is still centered on the chuck, after performing step (b), so as to form a circumferential edge surface adjacent said first curved surface and to separately form a frusto-conical surface adjoining said circumferential edge surface and opposite the peripheral portion of said first curved surface.

2. A method according to claim 1 wherein the second curved lens surface is cut by removing the partly worked blank after machining the peripheral edge portion, remounting it in the lathe or in another lathe and machining the second curved lens surface so that the second curved lens surface leads into the frusto-conical surface.

3. A method of manufacturing a contact lens comprising the steps of:

a. providing a contact lens blank,

b. rotatably mounting said blank in a material removal machine provided with at least a first material removal tool adapted to move in an arc and a second material removal tool means,

c. machining said mounted blank with said first tool to form a first curved lens surface,

d. machining a peripheral portion of said mounted blank with said second tool to form a circumferential edge surface,

e. machining a frusto-conical surface on said blank opposite and concentric with said first curved lens surface and adjacent said edge surface, and

f. machining a second opposite curved lens surface adjoining said frusto-conical surface.

4. A method according to claim 3, wherein said blank is rotatably mounted in a first position in said machine while said first curved surface and said peripheral edge portion are machined.

5. A method according to claim 4, wherein said blank is maintained in said first position in said machine while said frusto-conical surface is machined, and thereafter the partly worked blank is removed from said first position and then rotatably mounted in a second position in the machine, said second surface being machined while the partly worked blank is in said second position.

6. A method according to claim 3 wherein the first curved lens surface is the concave surface of the lens and the frusto-conical surface is an external frusto-conical surface.

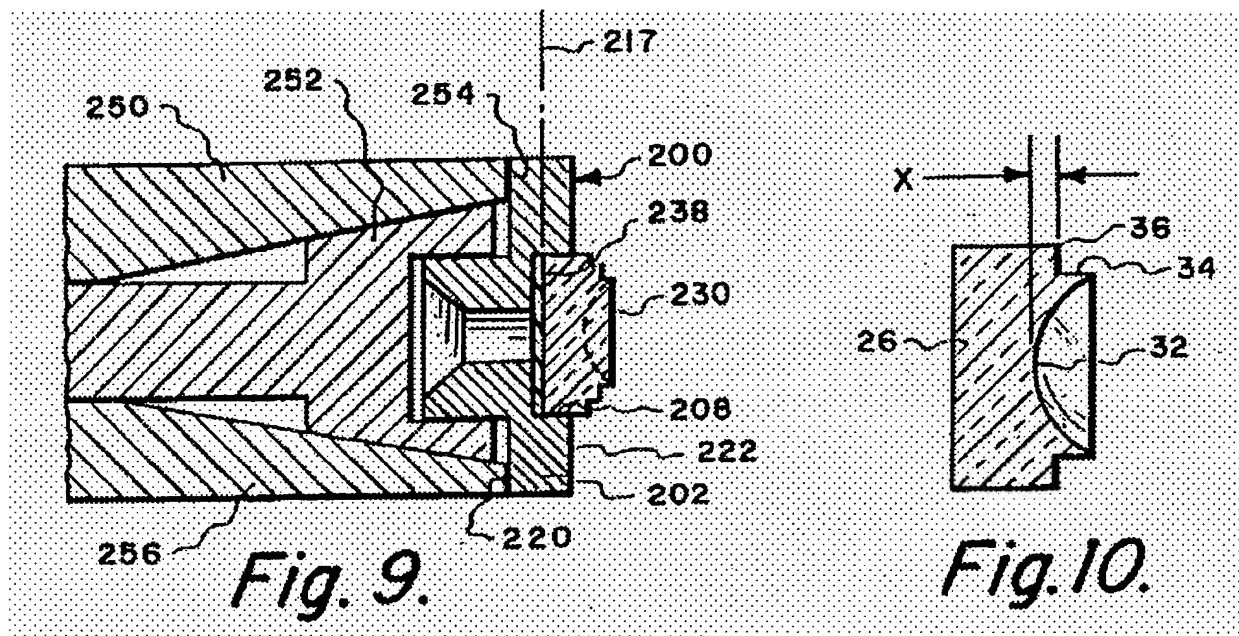
7. A method according to claim 6 including viewing the crown of the machined first, concave lens surface through the body of the partly worked blank in a direction perpendicular to the lens axis to determine the position of said crown relative to a further working tool, setting said further tool in accordance with said determined position, and then machining said second, convex lens surface by means of said further tool to provide a lens of predetermined thickness dimension.

8. A method according to claim 3 wherein the second material removal tool means comprises an edge cutting tool adapted to form said circumferential edge surface and a further cutting tool adapted to form said frusto-conical surface.

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11. Claims 46-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Vernon's 5,474,489.

With reference to Figure 9-10, Vernon discloses the claimed invention.



Claim Rejections - 35 USC § 103

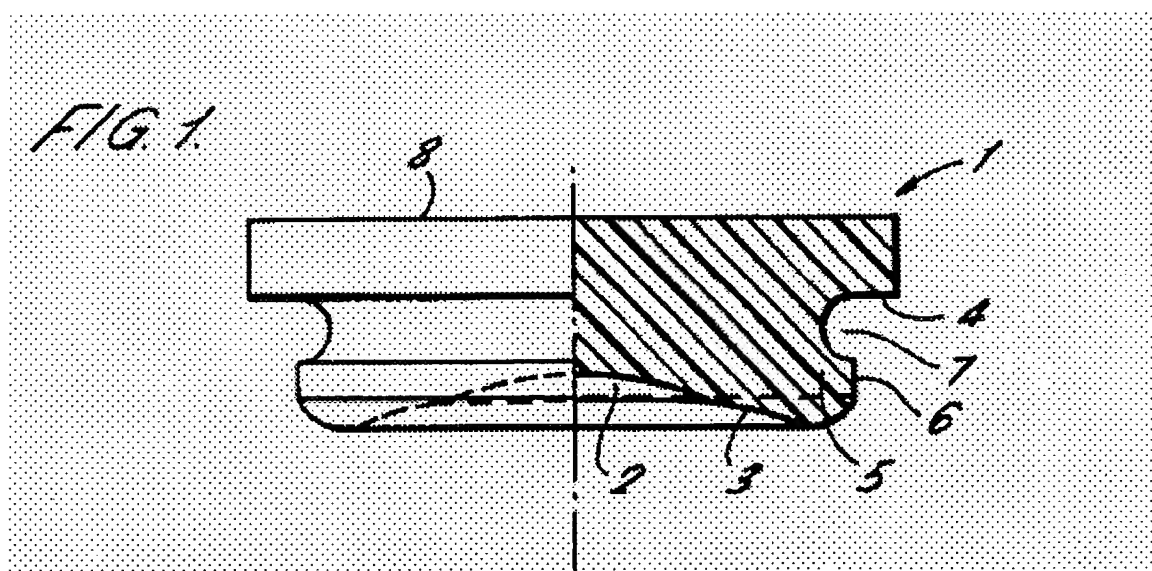
12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 19-21 and 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Galley' 4,084,458 in view of Dent et al.' 4,619,082.

With reference to Figure 1, Dent teaches a lens blank 1 having pre-formed reference surface 4 adapted for accurate mounting on a workholder 10 such that blank 1 is held with its first surface 2/3 accurately positioned relative to a datum point on the lathe in order to machine a second face 8 on blank 1. Such method avoids the need for skilled operatives and enables easy manufacture of accurately dimensioned contact lenses.

A contact lens is manufactured by a method involving machining a first face (2,3) and a reference surface (4) on a blank (1); mounting the blank (1) in a work holder (10) adapted for accurate mounting on a lathe such that the blank (1) is held with its first face (2,3) accurately positioned relative to a datum point on the lathe; and machining a second face (8) on the blank (1). Such method avoids the need for skilled operatives and enables easy manufacture of accurately dimensioned contact lenses.



Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Galley's lens blank with a pre-formed lens blank as taught by Dent because such modification would avoid the need for skilled operatives and enable easy manufacture of accurately dimensioned contact lens (the Abstract).

Regarding to claims 19-21, reference surface 4 is optical because of its transparent material, and mechanical because of its force fit connection to workholder 10.

Allowable Subject Matter

14. Claims 6, 12-15, 22, and 39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

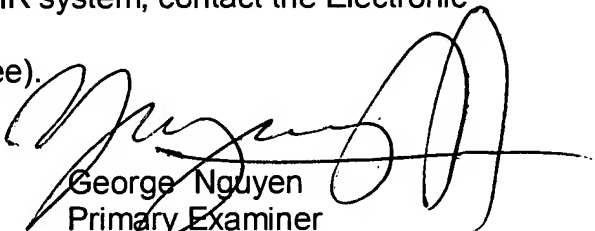
15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Nagaura'890 discloses method of machining both faces of lens by employing a sacrificial material. Vernon et al.'076 discloses self-aligned lens manufacturing system and method. Goins'234 discloses optical lens manufacturing apparatus and method employing a lens carrier for holding an optical lens blank. Schneider'741 discloses an apparatus for protecting the edge geometry of an intraocular lens.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Nguyen whose telephone number is 571-272-4491. The examiner can normally be reached on Monday-Friday/630AM-300PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Hail can be reached on 571-272-4485. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

George Nguyen
Primary Examiner


George Nguyen
Primary Examiner
Art Unit 3723

GN – June 29, 2005